

Attorney Docket No.: 10473.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Viksoe-Nielsen et al. Confirmation No: 3643

Serial No.: 10/561,671 Group Art Unit: 1651

Filed: December 20, 2005 Examiner: S. Macauley

For: Starch Process

APPEAL BRIEF UNDER 37 C.F.R. 41.37

Board of Patent Appeals and Interferences
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby appeal from the final rejection of claims 47-59 in the present application.

I. REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Novozymes A/S.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences relating to the instant application.

III. STATUS OF THE CLAIMS

Claims 47-59 and 61-65 remain pending in the application. Claims 1-46 and 60 have been canceled. Claims 61-65 have been withdrawn. Claims 47-59 (a copy of which is included in the Claims Appendix) are included in this appeal.

IV. STATUS OF AMENDMENTS

The reply filed under 37 C.F.R. § 1.116 on October 13, 2010 was considered, but has been stated as not overcoming the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 47 is the only independent claim in this appeal. As described at page 2, lines 10-19 of the specification, the subject matter of claim 47 is directed to a process for producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature of said granular starch to the action of a first enzyme and a second enzyme. The term "initial gelatinization temperature" is defined at page 3, lines 19-27 of the specification as "the lowest temperature at which gelatinization of the starch commences."

The first enzyme used in the process is a member of the Glycoside Hydrolase Family 13; has alpha-1,4-glucosidic hydrolysis activity; and comprises a functional carbohydrate-binding module belonging to CBM Family 20, wherein the carbohydrate-binding module comprises an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 2.

"Glycoside Hydrolase Family 13" is defined at page 4, lines 1-4 as a group of hydrolases comprising a catalytic module having a (beta/alpha)₈ or TIM barrel structure and acting on starch and related substrates through an alpha-reacting mechanism (Koshland, 1953, *Biol. Rev. Camp. Philos. Soc.* 28: 416-436).

Enzymes having "alpha-1,4-glucosidic hydrolysis activity" are defined at page 4, lines 5-9 as a group of enzymes which catalyze the hydrolysis and/or synthesis of alpha-1,4 glucosidic bonds as defined by Takata et al. (*J. Biol. Chem.* 267: 18447-18452 (1992)) and Koshland (*Biol. Rev. Camp. Philos. Soc.* 8: 416-436 (1953)).

The second enzyme may be a fungal alpha-amylase, a beta-amylase, or a glucoamylase. See, e.g., pages 8 and 9 of the specification.

VI. CONCISE EXPLANATION OF EACH GROUND OF REJECTION

The grounds of rejection to be reviewed on appeal and a concise explanation thereof are as follows:

1. Whether claims 47-56 are rendered obvious under 35 U.S.C. § 103 over Shi et al. (U.S. Patent No. 6,054,302) in view of Walon (U.S. Patent No. 4,235,965), as evidenced by the sequence alignment designated Alignment 1.
2. Whether claims 47-59 are rendered obvious under 35 U.S.C. § 103 over Shi et al. (U.S. Patent No. 6,054,302) in view of Walon (U.S. Patent No. 4,235,965), as evidenced by the

sequence alignment designated Alignment 1, and further in view of Leach (U.S. Patent No. 3,922,196).

VII. ARGUMENT

A. Claims 47-56 are not obvious over Shi et al. in view of Walon, as evidenced by the sequence alignment designated Alignment 1

1. Summary of the Rejection

Claims 47-56 are rejected under 35 U.S.C. 103 as being unpatentable over Shi et al. (U.S. Patent No. 6,054,302) in view of Walon (U.S. Patent No. 4,235,965), as evidenced by the sequence alignment designated Alignment 1.

According to the Office, Shi et al. disclose a method of producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature to the action of two or more enzymes such as an alpha-amylase, beta-amylase or glucoamylase and Walon teaches a method for producing a soluble starch hydrolysate by subjecting a granular starch slurry at a temperature below its initial gelatinization temperature to a bacterial alpha amylase.

However, as the Office concedes, neither Shi et al. nor Walon teach or suggest the use of an enzyme which (i) is a member of the Glycoside Hydrolase Family 13; (ii) has alpha-1,4-glucosidic hydrolysis activity; and (iii) comprises a functional carbohydrate-binding module belonging to CBM Family 20, wherein the carbohydrate-binding module comprises an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 2, as claimed herein.

Nevertheless, the Office states that “One of ordinary skill in the art would have been motivated to use an enzyme comprising the CBM recited in the claims because an enzyme comprising the CBM recited in the claims is an alpha amylase from a *Bacillus* spp. (see attached Alignment 1).” This is respectfully traversed.

2. Law on Obviousness

It is well settled that the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. See *Oetiker*, 977 F.2d at 1445; see also *Piasecki*, 745 F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *Id.*

3. Applicants' Arguments for Patentability

Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness.

Alignment 1 provides the results of a search in the GenCore database for references disclosing a carbohydrate binding domain having the amino acid sequence of SEQ ID NO: 2. The search identified the following eight references disclosing a carbohydrate binding domain with 100% sequence identity to SEQ ID NO: 2:

1. WO 2004/113551 (result 1)
2. WO 2005/003311 (result 2)
3. WO 2005/045018 (result 3)
4. WO 2005/069840 (result 4)
5. WO 2006/065579 (result 5)
6. WO 2007/149699 (result 6)
7. WO 2004/113551 (result 7) and
8. WO 2005/001064 (result 8).

However, all of these references published after the filing dates of the Danish applications (namely, Danish application nos. PA 2003 00949 and PA 2003 01568 filed June 25, 2003 and October 24, 2003, respectively) and US provisional applications (namely, U.S. Application Nos. 60/482,589 and 60/514,854 filed June 25, 2003 and October 27, 2003, respectively), priority or the benefit of which is claimed under 35 U.S.C. 119. All of the references also published after the filing date of international application no. PCT/DK2004/000456, from which the present application was filed under 35 U.S.C. 371. Therefore, these references are not prior art.

In response to Applicants' arguments, the Office stated that "the alignment is cited only to provide evidence of inherent characteristics of prior art *Bacillus* enzymes, and need not itself be a prior art reference."

However, in order to establish a *prima facie* case of obviousness, the Office has the burden to identify a prior art reference which discloses an enzyme which comprises a carbohydrate-binding module with at least 90% homology to the amino acid sequence of SEQ ID NO: 2. The Office has not met its burden. There are many known *Bacillus* enzymes, but there is no evidence that an enzyme comprising a carbohydrate-binding module of SEQ ID NO: 2 was in the prior art.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants therefore respectfully request reversal of the rejection.

B. Claims 47-59 are not obvious over Shi et al. in view of Walon, as evidenced by the sequence alignment designated Alignment 1, and further in view of Leach

1. Summary of the Rejection

Claims 47-59 are rejected under 35 U.S.C. 103 as being unpatentable over Shi et al. (U.S. Patent No. 6,054,302) in view of Walon (U.S. Patent No. 4,235,965), as evidenced by the attached sequence alignment (Alignment 1), and further in view of Leach (U.S. Patent No. 3,922,196). This rejection is respectfully traversed for the reasons of record.

The Office applied Shi et al., Walon, and Alignment 1 as provided in the 103 rejection discussed above. According to the Office, Leach teaches a method for the enzymatic hydrolysis of granular starch wherein the process may occur in the presence of a membrane, such as an ultrafiltration membrane, wherein the retentate is held in the presence of membranes and the permeate is the soluble starch hydrolysate.

2. Applicants' Arguments for Patentability

Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness.

As discussed above, Shi et al. and Walon do not teach or suggest an enzyme comprising a carbohydrate binding module recited in the claims. Moreover, the sequences set forth in Alignment 1 are not prior art.

Like Shi et al. and Walon, Leach does not teach or suggest an enzyme comprising a carbohydrate binding module recited in the claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants therefore respectfully request reversal of the rejection.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the appeal is provided in the Claims Appendix attached hereto.

IX. EVIDENCE APPENDIX

Applicants are not relying on any evidence submitted pursuant to 37 C.F.R. 1.130, 1.131, and 1.132 of this title or on any other evidence in the appeal.

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals and interferences pursuant to 37 C.F.R. 41.37(c)(1)(ii).

XI. CONCLUSION

For the foregoing reasons, Applicants submit that claims 47-59 are not rendered obvious by the cited references. Accordingly, the final rejection of the claims should be reversed.

Respectfully submitted,

Date: May 13, 2011

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CLAIMS APPENDIX
Copy of Claims Involved in the Appeal

Claim 47. A process for producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature of said granular starch to the action of a first enzyme and a second enzyme, wherein:

- (a) the first enzyme
 - (i) is a member of the Glycoside Hydrolase Family 13;
 - (ii) has alpha-1,4-glucosidic hydrolysis activity; and
 - (iii) comprises a functional carbohydrate-binding module belonging to CBM Family 20, wherein the carbohydrate-binding module comprises an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 2; and
- (b) the second enzyme is a fungal alpha-amylase, a beta-amylase, or a glucoamylase.

Claim 48. The process of claim 47, wherein the carbohydrate-binding module comprises an amino acid sequence having at least 95% homology to the amino acid sequence of SEQ ID NO: 2.

Claim 49. The process of claim 47, wherein the starch slurry has 20-55% dry solids granular starch.

Claim 50. The process of claim 49, wherein at least 85% of the dry solids of the granular starch is converted into a soluble starch hydrolysate.

Claim 51. The process of claim 47, further comprising subjecting the granular starch slurry to the action of an isoamylase or a pullulanase.

Claim 52. The process of claim 47, wherein the temperature is at least 58°C.

Claim 53. The process of claim 47, wherein the pH is in the range of 3.0 to 7.0.

Claim 54. The process of claim 47, wherein the soluble starch hydrolysate has a DX of at least 94.5%.

Claim 55. The process of claim 47, wherein the granular starch is obtained from tubers, roots, stems, whole grain, corn, cobs, wheat, barley, rye, milo, sago, cassava, tapioca, sorghum, rice or potatoes.

Claim 56. The process of claim 47, wherein the granular starch is obtained from dry milling of whole grain or from wet milling of whole grain or from milled corn grits.

Claim 57. The process of claim 47, wherein the process is conducted in an ultrafiltration system and where the retentate is held under recirculation in presence of enzymes, raw starch and water and where the permeate is the soluble starch hydrolysate.

Claim 58. The process of claim 47, wherein the process is conducted in a continuous membrane reactor with ultrafiltration membranes and where the retentate is held under recirculation in presence of enzymes, raw starch and water and where the permeate is the soluble starch hydrolysate.

Claim 59. The process of claim 47, wherein the process is conducted in a continuous membrane reactor with microfiltration membranes and where the retentate is held under recirculation in presence of enzymes, raw starch and water and where the permeate is the soluble starch hydrolysate.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None